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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 13 1980

OFFICE OF TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Meeting Summary--OTE Disposition of PRL-1 Report on Asbestos-Contaminated Vermiculite

FROM: Joseph J. Merenda, Director
Assessment Division

JMerenda

TO: Warren R. Muir, Deputy Assistant Administrator for Testing and Evaluation

On June 12, 1980, the DAA/OTE met with representatives of the Assessment Division (AD), the Health Review Division (HRD), and the DAA's Senior Medical Adviser to discuss the disposition of AD's Priority Review Level 1 (PRL-1) report on asbestos-contaminated vermiculite. The Environmental Review Division (ERD) did not attend but earlier provided comments to AD agreeing with the report's conclusions.

After discussion of various aspects of the vermiculite problem, the following decisions were made by the DAA/OTE:

1) The recommendations on pps. 24-27 of the PRL-1 report were adopted. Implementation of Recommendation C., initiate pre-regulatory control options analysis, will be done first through prompt consideration by the Section 6 Policy Group. AD will provide copies of the PRL-1 to policy group members.

2) Decisions on the scope and manner of implementation of recommendations A and B (data gathering and analysis) will follow decisions on the TSCA role in taking action on asbestos-contaminated vermiculite.

3) AD will discuss with Jim Reisa mechanisms for getting ORD research initiated on the health effects of vermiculite (as opposed to asbestos) fibers.

cc: E. Barrera
J. Ficke
R. Guimond
C. Mapes
J. Reisa
J. Rowe
M. Segal
J. Seifter

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 5 1980

OFFICE OF TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Priority Review Level-1 (PRL-1) Report - Asbestos-Contaminated Vermiculite

FROM: Joseph J. Merenda, Director
Assessment Division (TS-792) Merenda

TO: Warren R. Muir
Deputy Assistant Administrator
for Testing and Evaluation (TS-792)

James Reisa, Acting Director
Health Review Division (TS-792)

John Ficke, Acting Director
Environmental Review Division (TS-792)

The attached PRL-1 report entitled Asbestos-Contaminated Vermiculite is being distributed for review within the Office of Testing and Evaluation. This chemical was referred to the Chemical Review and Evaluation Branch for consideration in the Priority Problem Assessment (PPA) process as a potential (backlog) 4(f) candidate. Consequently, the attached document does not address all potential sources and effects of the chemical. Instead, it addresses only those sources and effects relevant to the identified priority problem; i.e., the risk of asbestos-related diseases among workers who mine and process vermiculite.

Based on my review of the PRL-1 report, I recommend that assessment activities be continued after completion of data gathering activities to provide additional exposure information relevant to an assessment of risk. In addition to the problem originally recommended for consideration, I also recommend that data gathering and subsequent assessment activities be expanded to include an evaluation of the risk to the general population through use of products containing asbestos-contaminated vermiculite. Because section 4(f) of TSCA is not applicable to the vermiculite problem (c.f., Meeting Summary for 4(f) Meeting, May 5, 1980), such assessment activities should enter the PRL-2 stage of the PPA process without further consideration of 4(f) applicability/criteria.

The Assessment Division will schedule a disposition meeting the week of June 9, 1980. This meeting will focus on the above recommendations and any issues and information needs (not addressed in the PRL-1 report) that would influence an OTE decision on whether (and how) to proceed in assessing this chemical.

AD requests that technical comments on the PRL-1 report be provided in writing by COB, June 10, so these can be reviewed by AD staff and, if necessary, discussed with the commentors before the disposition meeting. Comments should be addressed to Elizabeth Barrera of AD. The disposition meeting should focus on what to do next, why, and how soon, not on a technical review of the document.

cc: C. Mapes
E. Barrera

DRAFT

PRIORITY REVIEW LEVEL 1 - ASBESTOS-CONTAMINATED VERMICULITE

June 1980

Assessment Division

Office of Testing and Evaluation

Office of Pesticides and Toxic Substances

U.S. Environmental Protection Agency

Washington, D.C. 20460

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EXECUTIVE SUMMARY

Vermiculite, a micaceous, hydrated, magnesium-iron-aluminum silicate, has been mined in the United States since 1929. W. R. Grace and Company has been the major domestic supplier of vermiculite since 1958 and currently markets 80% of the vermiculite used in the U.S. W.R. Grace & Company acknowledged the presence of asbestos in the vermiculite from their Libby, Montana mine in 1971, and in 1977, an EPA study reported the presence of substantial amounts of asbestiform amphibole fibers in the tailings (residues) from the Libby, Montana mining and milling operations. After mining, vermiculite is processed to remove impurities; however, attempts to remove all contaminants have been unsuccessful and tremolite asbestos remains as a contaminant in the vermiculite obtained from the Libby mine at a concentration of at least 1%.

Vermiculite is distributed in commerce either as raw ore or in an expanded (exfoliated) form. Crude, unexfoliated vermiculite is used in the manufacture of gypsum wallboard, coatings, adhesives, cinder blocks, and paper products. Exfoliated vermiculite is used primarily in loose fill and block insulation as thermal insulators, in concrete aggregates, as a fertilizer carrier, in horticulture and soil conditioning, and in premixed aggregates. In 1977, about 21,000 long tons of crude vermiculite and 320,854 short tons of exfoliated vermiculite were consumed in the U.S.; the largest increases in vermiculite uses have been in loose fill insulation and fertilizer.

Worker exposures to asbestos-contaminated vermiculite can occur during both mining and processing of this substance. Additional worker exposures to asbestos-contaminated vermiculite may occur during use of the material but are not addressed in this assessment. Although identified vermiculite mining and processing companies insist that their employees currently are exposed to asbestos levels within the prescribed OSHA asbestos workplace standard of 2 million fibers per cubic meter (2 f/cm^3), available monitoring data indicate that workers have been exposed to asbestos fiber levels as high as 245 f/cm^3. The average workplace exposure, however, may be considerably lower based on monitoring data for certain mining operations: 0.3 - 2.6 f/cm^3 in ambient air surrounding the Libby, Montana mine; 0.6-1.8 f/cm^3 for equipment operators; and 0.2-5 f/cm^3 for employees in loading areas. In addition to worker exposures, a substantial portion of the general population also is potentially exposed to asbestos-contaminated vermiculite because certain consumer products (lawn care products) may contain large quantities (i.e., about 50%) of vermiculite (Thompson 1979).

In December 1978, O.M. Scott & Sons submitted information to the EPA regarding health problems experienced by employees who were processing asbestos-contaminated vermiculite. The original submission indicated that bloody pleural effusions had been detected in 4 of 350 employees; symptomatology and clinical findings in the employees were similar to those found in individuals with asbestos-related diseases. Subsequent follow-up studies by the Occupational Safety and Health Administration (OSHA) revealed that the prevalence of health problems among employees at O.M. Scott & Sons was greater than originally expected. Thirty-two cases of pleural and/or interstitial abnormalities were detected by chest X-rays and/or spirometric measurements (X-rays were taken for 125 of 221 workers).

Because there are no published reports on the health effects of either "pure" vermiculite (fibrous or nonfibrous) or asbestos-contaminated vermiculite, medical records of four Scott employees that developed pleural abnormalities as well as data on the health effects associated with asbestos exposure (cancer and asbestosis) were used to evaluate the potential risk to workers who mine and process asbestos-contaminated vermiculite. EPA risk estimates, based on asbestos exposure, project that 1 of every 10 workers exposed to 2 f/cm^3 (or 1 of every 200 workers exposed to 0.1 f/cm^3) for 50 years will die prematurely from an asbestos-related disease.

In summary, there is evidence that asbestos is present in vermiculite obtained from W. R. Grace & Company's Libby, Montana mine and that the health problems experienced by the employees of one processor of vermiculite from the Libby mine (O. M. Scott & Sons) are comparable with those associated with asbestos exposure. Risk estimates calculated for exposure to asbestos, at fiber levels within the ranges reported for vermiculite mining and processing operations, suggest that asbestos-contaminated vermiculite may pose a serious and widespread hazard to workers. However, in the absence of data on exposure of employees in other vermiculite mining and processing operations or of asbestos contamination levels of vermiculite from other sources, it is not possible to fully evaluate the risks to workers in all vermiculite industries. However, the extent of exposure from vermiculite derived from the Libby mine is likely to be large, considering that this source accounts for approximately 80% of the vermiculite used in the U.S.

I. BACKGROUND

A. Problem Identification. The Chemical Hazard Identification Branch (CHIB) of the Assessment Division in the Office of Pesticides and Toxic Substances (OPTS) received information, in December 1978, from the vermiculite industry indicating that four cases of bloody pleural effusions of the lungs and one possible case of asbestosis had been detected among 350 employees at the O.M. Scott & Sons chemical fertilizer plant in Marysville, Ohio. This plant uses vermiculite, some of which is contaminated with tremolite asbestos, as a substrate for its commercial lawn care products (O.M. Scott & Sons 1978). Subsequent to its preparation of a priority Chemical Hazard Identification Profile (CHIP) on vermiculite, CHIB, with the concurrence of the Environmental and Health Review Divisions, referred the problem to the Chemical Review and Evaluation Branch (CREB) for Priority Problem Assessment. The specific problem to be evaluated was the potential risk of asbestos-related diseases among workers who mine and process asbestos-contaminated vermiculite.

B. Mineralogy. Vermiculite is a micaceous, hydrated, magnesium-iron-aluminum silicate with a lamellar (plate-like) structure (Swensson 1975). This mineral, which is related to and often associated with asbestos, has been referred to as zonolite (W.R. Grace & Company 1979), Verxite[R] (Hawley 1977) and phyllosilicate clay (Douglas 1977); it can be found in nonfibrous and fibrous forms (Marshall 1977). Commercially, "vermiculite" includes any micaceous mineral that can expand, regardless of its chemical composition or the regularity of its crystal structure (Brobst and Pratt 1973). Pure vermiculite can be expanded (exfoliated) up to 30 times its original volume when heated to 1,000-2,000°F, though impure varieties expand less (Otis 1959).

The world's largest vermiculite deposit is in Libby, Montana. Other deposits, in order of significance to the U.S. industry, are in the Palabora region of northeastern Transvaal, South Africa, South Carolina (Inner Piedmont Province), Virginia (Blue Ridge Province), North Carolina, and Georgia. Scattered deposits also are located in Wyoming, Texas, Colorado, California, Nevada, Arizona, Washington, and Oregon (Brobst and Pratt 1973). Weathering processes may result in the formation of other co-existing mineral phases, predominantly hydrous, magnesium silicates (anthophyllite, tremolite, serpentine and chrysotile minerals) which occur as intergrowths, microscopic nodules or discrete zones within or adjacent to vermiculite.

These silicates can occur in nonfibrous and fibrous forms. The intergrowth of the fiber is such that even extensive purification (beneficiation) may not yield a pure product. Where the fine-grained intergrowths occur, the processed products will likely contain residual tremolite (Rohl et al. 1977). Talc or tremolite deposits may occur geologically in such close juxtaposition to chrysotile or other ore bodies that contamination of talc or tremolite with serpentine, dolomite, magnetite, pyrophyllites and clays may occur (Schepers 1965). This has been shown to be true of the Libby, Montana mining site (Eaton 1979).

An electron microscopic analysis by OSHA of vermiculite samples from the Libby, Montana, mine revealed the presence of tremolite asbestos (Dixon 1980). Substantial amounts of asbestiform amphibole fibers also have been found in tailings (residues) from the Libby mine (Stewart 1976). In addition, the proposed Big Springs, Virginia vermiculite mine was found to be contaminated with asbestos (Hamer 1977).

Vermiculite from the Palabora, South Africa, mine also has been analyzed using electron microscopic techniques. Data from these studies (Chatfield and Lewis 1979, Wisenbaker and Arnold 1976) show no positive identification of asbestos in the samples of raw or exfoliated vermiculite from the Palabora mine. Some fiber-like material, morphologically similar to chrysotile asbestos fibers, was examined and found to be more likely fragments of vermiculite "scrolls" which occur in vermiculite flakes. The authors reported concentrations of 1.3 ppm, 0.6 ppm and 0.2 ppm for this fibrous material intercalated between flakes of raw vermiculite, from raw vermiculite dust, and from exfoliated vermiculite, respectively. No amphibole asbestos (detection limits 0.8 ppm in intercalated samples and 0.007 ppm in dust) was observed. Thus, evidence to date suggests that the Palabora, South African mine is essentially free of asbestiform fibers and has low concentrations of other fibrous materials.

C. <u>Monitoring and Measuring Asbestos Contamination</u>. The current OSHA limit on occupational exposure to asbestos fibers is an 8-hour time-weighted average of 2 fibers per milliliter (2 million fibers per cubic meter, 2 f/cm^3), no longer than 5 micrometers with a length-to-width ratio of at least 3:1 detected by a method using phase contrast (optical) microscopy (OSHA 1972). A disadvantage in using phase-contrast optical microscopy, rather than the higher resolution electron microscopy (which is more time-consuming and expensive), is that it is not possible to count all the fibers in a given sample. Additionally, it is not always possible to distinguish between asbestos and other fibers using optical microscopy.

Personal and environmental monitoring samples were taken and analyzed at the O.M. Scott & Sons, Marysville, Ohio plant and at the W.R. Grace & Company's Libby, Montana mine, using the standard optical microscopy method described above (O.M. Scott & Sons 1978, W.R. Grace & Company 1979). Although the submissions from both companies refer to measured fiber levels as asbestos fiber levels, it is important to note that fibers other than asbestos (e.g., vermiculite or other mineral fibers) may have been counted in the samples analyzed by these companies. This statement is based on the following factors: vermiculite occurs in fibrous and nonfibrous forms; electron microscopic analyses were used only occasionally to evaluate and identify the fibers in the samples; and no fiber size distribution was done on the "asbestos" found in the vermiculite samples.

D. <u>Historical Background</u>. Vermiculite has been mined in the United States since 1929 (Brobst and Pratt 1973). W.R. Grace & Company has accounted for the majority of the vermiculite supplied in the United States since 1958, and currently markets 80% of the vermiculite in the U.S. (Eaton 1979). W.R. Grace & Company acknowledged the presence of asbestos in the vermiculite from their Libby, Montana mine in 1971 (Hamer 1977), and in 1977, an EPA study reported the presence of substantial amounts of asbestiform amphibole fibers in the tailings (residues) from the Libby mining and milling operation (Stewart 1976).

For the past twenty years, O.M. Scott & Sons has received at least 50% of their vermiculite from the Libby mine and the remaining 50% from the Palabora Mining Company, South Africa (O.M. Scott & Sons 1978). Previous asbestos exposure levels in the trionizing area were reportedly 100 times the current OSHA workplace standard of 2 million fibers per cubic meter, however, the advent of better control technology (e.g., erection of a wall separating departments, enclosed conveyors, equipment, and machinery plus the use of respirators) has substantially lowered the fiber levels (O.M. Scott & Sons 1978).

In 1978, O.M. Scott & Sons submitted information indicating that four cases of bloody pleural effusions of the lungs and on possible case of asbestosis had been detected at their chemical fertilizer plant. Soon after the health problems at O.M. Scott & Sons were reported, OSHA initiated a preliminary medical investigation (chest X-ray examinations) of the Scott employees which revealed an additional 32 cases of pleural abnormalities of varying degrees (Brooks and Smith 1979). Studies have shown that not only are pleural effusions an indication of a toxic effect in the lungs or surrounding tissue, they also are a typical reaction to asbestos exposure (Preger 1978). Bloody pleural effusions can be an early sign of pleural mesothelioma in humans occupationally exposed or para-occupationally exposed to asbestos (Selikoff 1978).

The asbestos contamination of vermiculite and health problems related to asbestos exposures have received considerable attention from the Federal sector during the past three years. Pertinent past and ongoing activities are summarized below.

1) Upon reviewing a request for a planned vermiculite mining site in Big Springs, Virginia, EPA received information that asbestos was present in that particular vermiculite deposit (Hamer 1977).

2) The Consumer Product Safety Commission (CPSC) considers vermiculite subject to inadvertent asbestos contamination and, together with EPA, has

published in the Federal Register an Advance Notice of Proposed Rulemaking, stating their intention to coordinate efforts with EPA to control human exposure to asbestos (CPSC 1979).

3) EPA's Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina, is evaluating new source performance standards on 18 minerals under Section 111 of the Clean Air Act (Public Law 91-604) to limit air emissions of vermiculite dust in crushing operations (Chaput 1979).

4) The asbestos in vermiculite is regulated by the Occupational Safety and Health Administration's (OSHA) Standard for Exposure to Asbestos Dust (37 FR 11318, June 7, 1972; 29 CFR Part 1910). This standard states that the 8-hour, time-weighted average (TWA) airborne concentrations of asbestos fibers to which any employee may be exposed shall not exceed 2 million fibers (longer than 5 micrometers) per cubic meter of air. OSHA is further investigating the occurrence of asbestos-related diseases in workers handling vermiculite at O.M. Scott & Sons (Alexander 1978).

II. EXPOSURE ANALYSIS

A. Production and Use. Vermiculite has a variety of physical properties that make it suitable for many different uses. It consists of thin, flat, mica flakes containing microscopic droplets of water. When the crude mineral is heated, its water of crystallization vaporizes and is trapped between the flakes. This causes the vermiculite to exfoliate and become light-weight (Swensson 1975). These special properties make it a prime candidate for the uses described in this section. Crude, unexfoliated vermiculite is used in the manufacture of gypsum wallboard, coatings, adhesives, cinder blocks and paper products (cardboard) for insulation purposes. It is also used as a plastics extender and as an ion-exchange agent in wastewater treatment (Haines 1977).

In 1977, approximately 21,000 long tons of crude vermiculite were consumed in the U.S. As shown in Table 1, 320,854 short tons of exfoliated vermiculite were used in 1977, primarily in loose fill insulation, in concrete aggregates, in block insulation, as a fertilizer carrier, in horticulture and soil conditioning, and in premixed aggregates (e.g., for acoustic and

Table 1. Distribution of Exfoliated Vermiculite Sold or Used in 1975-1977

Application	1975 Short tons	1975 Percent of total	1976 Short tons	1976 Percent of total	1977 Short tons	1977 Percent of total
Aggregates:						
Concrete	75,000	32	67,706	25	65,920	21
Plaster	4,000	1	3,099	1	3,599	1
Premixes[a]	38,000	17	39,448	15	30,130	9
Subtotal	117,000	50	110,253	41	99,649	31
Insulation:						
Loose fill	39,000	16	39,058	14	74,900	23
Block	35,000	15	39,310	15	50,980	16
Packing	---	--	390	--	168	--
Subtotal	74,000	31	78,758	29	126,048	39
Agriculture:						
Horticulture and soil conditioning	31,000	13	36,379	13	40,780	13
Fertilizer carrier	7,000	3	37,450[b]	14	47,580	15
Subtotal	38,000	16	73,829[b]	27	88,360	28
Miscellaneous:	6,000	3	7,334	3	6,797	2
Total	235,000	100	270,174	100	320,854	100

Source: Haines 1977.

a Includes vermiculites used in premixes for acoustic and fireproofing purposes, decorative textures, moisture sealants, etc.

b Revised.

fireproofing purposes, decorative textures and moisture sealants). The largest increases in use have been in the loose fill insulation and fertilizer carrier lines (Haines 1977).

B. Potential Occupational Exposure. Asbestos contamination of vermiculite deposits is dependent on the geological setting of the deposit. Where asbestos is found as a contaminant in a vermiculite deposit, exposure to both asbestos and vermiculite may occur during mining and processing of the vermiculite. There are no federal standards or limits on exposure to vermiculite per se; however, the tremolite asbestos-contaminated vermiculite mining and processing operations are subject to the same regulations as those applied to the mining and milling of commercial asbestos.

Exposure During Mining.* Vermiculite is obtained by strip-mining techniques using heavy earth-moving equipment. In the past, mining employees have been exposed to asbestos-containing fiber levels in excess of the current OSHA standard of 2 f/cm^3 (W.R. Grace &

* The data on worker exposures during mining, processing-beneficiation and screening are from the submissions of W.R. Grace & Company which markets 80% of the vermiculite in the U.S.

Company 1979).+ Current levels in the ambient air surrounding the Libby, Montana mine range from 0.3 to 2.6 f/cm^3 (W.R. Grace & Company 1979). Equipment operator levels, lower today than in the past because of the use of enclosed equipment and machinery, range from 0.6 to 1.8 f/cm^3 (W.R. Grace & Company 1979). After mining, the vermiculite ore is put into sealed containers and transported to the beneficiation (purification) plant.

Exposure During Processing.

Beneficiation: During beneficiation, impurities in the raw vermiculite ore are physically separated by screening and washing. Before 1959, vermiculite ore was beneficiated by dry methods in which screens, direct-fired dryers, pneumatic tables, and air separators were used. To reduce the dust levels to which employees were exposed, these methods were replaced by a "wet" process in which adhering clay and other impurities are removed by washing. The nonexpandable, very fine fibrous and nonfibrous forms of vermiculite are removed by a rock-rejection procedure, and the ore is then concentrated and dried. Attempts to remove all contaminants from the vermiculite have been unsuccessful and, tremolite

+ The current asbestos OSHA workplace standard of 2 f/cm^3 is used for comparative purposes only. The reader should note the existing health risk at this level of asbestos exposure (see page 21).

asbestos remains as a contaminant in the vermiculite obtained from the Libby mine at a concentration of at least 1% (W.R. Grace & Company 1979).

<u>Screening</u>: At the screening plant, the unexfoliated vermiculite ore is separated into five sizes, packaged, loaded onto railroad cars and sent to distributors, who either exfoliate it or sell the concentrate as is. Available data show that the raw vermiculite ore is mined, beneficiated, and screened in Montana and/or South Africa and shipped to expanding (exfoliation) plants such as O.M. Scott & Sons in Marysville, Ohio. Employees in the loading area are exposed to fiber levels that range from 0.2 to 5 f/cm^3 (W.R. Grace & Company 1979).

<u>Trionization process</u>:* Scott has been using the trionizing process to manufacture its lawn care products for 20 years. In these products, vermiculite is an inert carrier for fertilizer chemicals or fertilizer plus pesticide chemicals. First, the ore is exfoliated with heat so that its layered structure unfolds in an accordion-like manner. This creates a greater surface area to which the chemicals can adhere. The exfoliated vermiculite usually is stored before the chemicals are added. After the chemicals are added, the material is

* The remainder of the processing section consists of data related specifically to operations performed at O.M. Scott & Sons.

packaged. Before 1976, employees working near or in the unloading area (where the unexfoliated ore was dumped from railroad cars) were exposed to asbestos fiber levels significantly above the 2 f/cm^3 OSHA standard; levels as high as 245 f/cm^3 were reported (O.M. Scott & Sons 1978). The unloading area was not separated from the trionizing area. In 1976, a wall was erected between these areas and enclosed conveyors were installed to transport the vermiculite, measures that reportedly have significantly lowered the fiber levels (O.M. Scott & Sons 1978).

<u>Packaging</u>: Sampling for total and respirable dust and total fibers (including asbestos) in the packaging area showed that levels are below 2 f/cm^3 when the bagging equipment and dust collecting equipment are working properly (O.M. Scott & Sons 1978).

<u>Maintenance</u>: Workers are exposed to the highest dust levels when the emissions control equipment, e.g., baghouse, air collecting fans, and ventilation systems, is being repaired. Although exposure levels during repair operations depend on the extent of the repair, and the housekeeping practices of the plant, they tend to be above the 2 f/cm^3 OSHA standard. Some plants which utilize vermiculite in their product are known to have "peak" seasons when production increases because of the

demand for the product. Maintenance of equipment and the frequency of repairs also may increase during this time, resulting in increased exposure of workers to asbestos (O.M. Scott & Sons 1978).

Disposal: Any fine dust generated during processing is washed into a wastewater stream that is recycled into the plant (O.M. Scott & Sons 1978). Water is employed in the wet milling operation as well as for carrying the mineral tailings to settling ponds. Local sources near the Libby mine supply the water, but the system is closed and there is no drainage into nearby streams or rivers (O.M. Scott & Sons 1978). Coarse tailings mixed with water are poured downhill into the first of two settling ponds where they are contained (Stewart 1976).

III. HEALTH EFFECTS

The identified health effects associated with exposure to vermiculite can be attributed to its asbestos contaminant. However, there is also the possibility that the presence of fibrous vermiculite and other fibrous materials may have enhanced the health problems. Epidemiologic research has identified cancers of the lung, pleura, peritoneum, larynx, oral cavity, esophagus, stomach, colon and kidney as hazards of asbestos exposure. Inhalation of asbestos also produces a noncancerous lung disease (asbestosis).

Dose-response relationships (increasing risk with increasing asbestos exposure) have been shown for lung cancer (Newhouse and Berry 1979), pleural and peritoneal mesothelioma (Hobbs et al. 1979), larynx cancer (Rubino et al. 1979), stomach cancer (Hammond 1979) and asbestosis (Liddell 1979). Support for a linear nonthreshold model of dose-response is provided by two studies of respiratory cancer (McDonald and Liddell 1979, Henderson and Enterline 1979) and one study of pleural mesothelioma (Hobbs et al. 1979) among asbestos workers. Three studies also exist which are consistent with a similar dose-response relationship between asbestos exposure and the risk of asbestosis (Liddell 1979, McDonald 1979, Berry et al. 1979).

These dose-response studies are supported by evidence of health effects resulting from relatively low levels of asbestos exposure. Workers exposed to asbestos for the equivalent of 5 years at the current workplace standard of 2 million fibers per cubic meter exhibit increased lung cancer risk. Mesothelioma, "a marker disease" (disease that is always, or nearly always, caused by a particular agent) for asbestos exposure, has occurred in persons with exposures as brief as one or two days and in persons with steady exposures as low as those found in the homes of asbestos workers and in the neighborhoods around asbestos mines, asbestos product factories, and shipyards. Signs of asbestosis also have been detected (by X-ray) among persons sharing households with asbestos workers actively employed for less than a year (Anderson et al. 1979). The occupational studies consistent with the linear nonthreshold dose-response model and the studies showing risks at exposure levels lower than those found in the workplace support the conclusion that asbestos exposure in the environment may be expected to produce adverse health effects.

There are no published reports on the health effects of either vermiculite alone (fibrous or nonfibrous) or vermiculite contaminated with asbestos. Therefore, the following discussion is based on the medical records of the four Scott employees that developed pleural abnormalities.

The possible adverse effect of exposure to asbestos-contaminated vermiculite was reported to the EPA in December, 1978, when O.M. Scott & Sons submitted information which stated that bloody pleural effusions (the presence of bloody fluid in the pleural space) had been detected in 4 of its 350 employees (O.M. Scott & Sons 1978). The pleural changes reported among these employees were similar to those observed among persons chronically exposed to asbestos minerals (chrysotile, amphiboles) or to geologically related minerals (mica, talc) (Preger 1978). The symptomatology and clinical findings in the four employees also are similar to those found in individuals with asbestos-related diseases (Preger 1978). The four employees reported symptoms such as cough, fatigue, dyspnea (shortness of breath), sweating, chest pain, hypotension, coryza (inflamed running nose), and a loss of appetite. Chest X-rays revealed the presence of fibrosis and pleural effusions.

Asbestos-related pleural effusions are difficult to diagnose because of the lack of attention that this manifestation of asbestos exposure has received. Even more difficult to diagnose are benign asbestos effusions. Up to 1977, only 50 cases of this asbestos-induced pleurisy had been diagnosed in the world. A common presenting feature is chest pain associated with moderate pleural effusion; the initial component in three of the four Scott employees. Recurrence of the effusion may occur (Preger 1978).

The interval between first asbestos exposure and the onset of disease is approximately 20 to 40 years, however, there are reported cases of intervals varying from 3.5 to 53 years after first exposure (Selikoff 1978). The occurrence of the four bloody pleural effusions was apparent in the Scott employees after 4-12 years of employment (O. M. Scott & Sons 1978).

The presence of bloody pleural effusions of the lung is an advanced stage of pleural disease with treatment ranging from, and including, thoracocenthesis (a surgical procedure performed to alleviate the pressure in the pleural cavity due to the increased amount of fluid) to pleurotomy (surgical incision of the pleura with scraping).

Although the amount of pleural fluid which can be removed in a healthy subject by thoracocentesis is 15 ml, no less than 50 ml and as high as 700 ml of bloody pleural fluid were removed from the four Scott employees (O.M. Scott & Sons 1978). Chest X-rays reveal that such effusions also may be accompanied by asbestosis (pneumoconiosis caused by inhalation of sufficient asbestos fibers to cause lung scarring), hyaline or calcified pleural plaques, and/or an exudative pleural rind (Preger 1978). Lung scarring has been noted in employees of W.R. Grace & Company (supplier for O.M. Scott & Sons), however, no evidence of disease in the Grace employees has been reported (Eaton 1979).

In January 1979, OSHA took chest X-rays and spirometric measurements of 108 of the 221 Scott workers employed in the trionizing, packaging, and maintenance departments, areas where the four afflicted workers had been employed. The most recent X-rays of 17 additional trionizing workers were obtained from the company's medical files and similarly reviewed and classified, thus, a total of 125 employee X-rays were reviewed. Thirty-two of the 125 X-rays were abnormal. The overall prevalence of pleural and/or interstitial abnormalities were found in 16 of the 41 trionizing workers that were examined; 7 of the 32 maintenance workers; and 9 of the 52 packaging workers. The proportion of these abnormalities increased with duration of employment for all departments. The proportion of abnormalities also increased with age (Brooks and Smith 1979).

IV. RISK EVALUATION

The high levels of asbestos fibers and the recent disclosure that the employees of O.M. Scott & Sons who handle asbestos-contaminated vermiculite have existing health problems suggest the possibility of a larger problem, e.g., risks to employees handling similar asbestos-contaminated vermiculite and to consumers exposed to products that contain asbestos-contaminated vermiculite.

Since 1956, Scott employees handling non-expanded vermiculite ore have been chronically exposed (continuous exposure to small amounts of contaminant over a long period) to asbestos (O.M. Scott & Sons 1978 and W.R. Grace & Company 1979) and Scott employees handling the expanded vermiculite ore have occasionally been acutely exposed (such as the exposure encountered by the workers in the trionizing area where measured asbestos exposure levels have been as high as 245 f/cm^3) to asbestos (O.M. Scott & Sons 1978).

Although the identified vermiculite miners and processors (W.R. Grace & Company and O.M. Scott & Sons) insist that the asbestos exposure levels are currently within the prescribed OSHA asbestos workplace standard of 2 f/cm^3 (2 million fibers per cubic meter), current EPA risk estimates project that 1 of every 10 workers exposed to this level of asbestos for 50 years will die prematurely from an asbestos-related disease (OTE 1980).

Using the asbestos exposure levels reported for W.R. Grace & Company and O.M. Scott & Sons employees and the linear nonthreshold model* one can derive risk estimates for workers handling asbestos-contaminated vermiculite. In the mining and screening of asbestos-contaminated vermiculite the workers are exposed to at least 0.1 f/cm^3. For a 50 year exposure at this level, 1 in 200 workers will die prematurely of an asbestos-related disease. Thus, whether the workers handling asbestos-contaminated vermiculite are exposed to 0.1 f/cm^3, 2 f/cm^3, or 100 times the OSHA workplace standard (e.g., in the trionizing department workers have been exposed to asbestos levels as high as 245 f/cm^3), there is potential for significant risk to workers handling asbestos-contaminated vermiculite.

* The linear nonthreshold model is being used by the Office of Testing and Evaluation/EPA to provide risk estimates in accordance with EPA Interim Guidelines for Carcinogenic Risk Assessment (41 FR 21402, May 25, 1976) and the Interagency Regulatory Liason Group's guidance (44 FR 39858, July 6, 1979).

Although such estimates indicate the potential magnitude of the health risk to workers handling asbestos-contaminated vermiculite, particularly those employed by W.R. Grace & Company and O.M. Scott & Sons, the extent of the risk associated with vermiculite mining and processing operations, in general, currently cannot be similarly evaluated for several reasons. These reasons are:

1) Information is available with respect to 600 employees (150 O.M. Scott & Sons employees and 450 W.R. Grace & Company employees) who mine and process asbestos-contaminated vermiculite from the Libby, Montana mine. For an indepth evaluation of risk, information also is needed on the number of employees exposed at the other expanding plants to which W.R. Grace & Company distributes, the content of asbestos in other vermiculite deposits (e.g., South Carolina, Virginia, Georgia and North Carolina) and the number of mining and processing employees exposed to vermiculite from these sources, if asbestos-contaminated.

2) The concentration of asbestos and the size distribution of the fibers in the asbestos-contaminated vermiculite to which workers are exposed must be better quantified for a detailed risk assessment.

3) The following factors suggest that the health effects seen in the Scott employees are caused by the asbestos in the vermiculite: a) asbestos is present in the vermiculite from the W.R. Grace & Company's Libby, Montana mine; b) the health problems observed among the O.M. Scott & Sons employees are comparable with those health problems associated with asbestos (bloody pleural effusions); c) there is no evidence to indicate that the health effects the workers are experiencing are not asbestos-related; and d) the fiber levels monitored at vermiculite mining and processing plants were equal to or greater than the OSHA workplace standard for asbestos exposure (2 million fibers per cubic meter). However, the possible fibrous nature of the vermiculite, other fibers in the material or a combination of asbestos and other fibers may contribute to the observed health effects. For purposes of a quantitative risk assessment of vermiculite, the identity of other fibers and their contribution to the health problems would require elucidation. However, for a risk assessment on asbestos-contaminated vermiculite, the causative agent can be assumed to be asbestos.

V. RECOMMENDATIONS

The recommendations presented below are based on the potential degree of risk of asbestos-related diseases among workers who mine and process asbestos-contaminated vermiculite and the adequacy of the available data on vermiculite for continuation of assessment activities.

A. Initiate data gathering activities. Most of the exposure information currently available is specific to the Libby, Montana mine which supplies 80% of the vermiculite that W.R. Grace & Company distributes in the U.S. This particular mine is known to be contaminated with asbestos and to supply 50% of the vermiculite used by O.M. Scott & Sons. However, other sources indicate that the Palabora Mine in South Africa (from which O.M. Scott & Sons obtains the remaining 50% of its vermiculite) may not be asbestos contaminated. The possiblity of asbestos contamination in other major vermiculite supplies, and the number of processors that these mines distribute to, are unknown. Therefore, to fully assess the degree of risk to workers who mine and process asbestos-contaminated vermiculite, the following information is needed:

1) identification of all major vermiculite deposits that contain asbestos and quantification of the asbestos content of these mineral deposits;

2) the vermiculite processors supplied by these mines;

3) the total number of employees exposed to asbestos-contaminated vermiculite in the vermiculite industry; and

4) personal and environmental monitoring data on the asbestos levels at the various vermiculite mining and processing sites.

Previous monitoring data and health records of employees exposed to asbestos-contaminated vermiculite, if available, also are of importance in determining whether an exposed population is still at risk and in determining and ruling out causative agents.

B. Expand data gathering activities and future assessment activities to evaluate the risk of asbestos-related diseases among consumers using products that contain asbestos-contaminated vermiculite. Because certain consumer products contain large quantities of vermiculite (e.g., wallboard and lawn care products), asbestos-contaminated vermiculite may pose a risk to the general population. Representatives of W.R. Grace & Company, for example, have reported that improper handling of certain products, such as wallboard could result in exposure to asbestos fibers above the current OSHA asbestos workplace standard of 2 f/cm^3 (Eaton 1979).

Specific information needed in this area includes:

1) the levels of asbestos contamination remaining in vermiculite after mining and processing;

2) identification of consumer products that contain vermiculite and quantification of the asbestos contamination in these products; and

3) information on the production and sales volumes of these products.

C. <u>Initiate pre-regulatory control options analysis.</u> The available data indicate that workers who mine or process vermiculite from W.R. Grace & Company's Libby, Montana mine are exposed thereby to asbestos levels that present a significant risk of serious asbestos-related diseases. Even in the absence of complete information on the size and exposure (risk) levels of this worker population, a preliminary analysis of the regulatory control options should be performed to help focus the type and depth of risk assessment activities that would be needed to support any regulatory action on this problem.

D. <u>Defer additional assessment activities until the control options analysis and/or data gathering activities are completed</u>.

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